media, transportation/POL and contingencies etc. This has resulted in increase in collection and preservation of donated eyes for better use.

Infant deaths due to clinical trials at AIIMS

*4. SHRI VIJAY JAWAHARLAL DARDA:
SHRI ABU ASIM AZMI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that as many as 49 babies had died at the AIIMS while being subjected to clinical trials for testing new drugs and therapies;

(b) if so, the details thereof;

(c) whether Government has set up a special committee to probe reports of the deaths of children during clinical trials at the hospital and asked them to submit report within a week;

(d) if so, the details of the report submitted by the committee;

(e) whether Government proposes to review the policy of clinical trials; and

(f) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (d) Death of 49 children enrolled in 6 clinical trials at All India Institute of Medical Sciences, New Delhi, was reported between January 2006 and June, 2008. These consisted of 4 clinical trials with drugs as interventions, one trial with feeding protocol and one with Continuous Positive Airway Pressure (CPAP). The Director, All India Institute of Medical Sciences (AIIMS), New Delhi, constituted a six member committee on 19th August, 2008, to inquire in the matter of clinical trials under the Chairmanship of Dr. Madhuri Behari, Professor and Head, Department of Neurology, AIIMS, New Delhi. The Committee scrutinized all the clinical trials including these 6 studies and submitted a report which observed that:

- All studies have scientific rationale and had undergone necessary scientific reviews.
- All Study protocols were approved by the Ethics Committee of AIIMS, New Delhi.
- Permission of Drug Controller General (I) were duly obtained where required.
- None of the deaths were attributable to the modalities tested and were due to underlying high risk illnesses and serious co-morbid disease conditions that the Children suffered from.
- None of the mortality rates reported under these trials is higher than that reported in patients with similar illnesses.

Presently, there is no proposal to review the policy of Clinical Trials.